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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/774,043

02/05/2004

Maheer N. Qabar

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04/07/2009

MYRIAD GENETICS INC.
INTELLECTUAL PROPERTY DEPARTMENT
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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

04/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/774,043 | Applicant(s) QABAR ET AL. | |
| | Examiner Phyllis G. Spivack | Art Unit 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-14, 30-45, 48-53 is/are pending in the application.
- 4a) Of the above claim(s) 30-32, 34-45 and 48-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-14, 33, 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The previous indication of finality is withdrawn.

Applicants' Amendment filed February 3, 2009 is acknowledged. Claims 46 and 47 are canceled. Claims 10-14, 30-45 and 48-53 remain under consideration. Applicants' Response filed March 2, 2009 to the Interview Summary is further acknowledged. Elections were made without traverse on March 7, 2008 of Group II, drawn to methods of inhibiting a kinase, and, as the elected specie, the compound of claim 33.

Methods of inhibiting a kinase comprising administering the compound of instant claim 33 remain under consideration, claims 10-14, 33 and 53. Those methods of use comprising administering compounds other than that of instant claim 33, and claims 30-32, 34-45 and 48-52, remain withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions.

A Terminal Disclaimer filed February 3, 2009 is acknowledged and accepted.

Applicants' list of co-pending and related applications is noted.

Those rejections set forth in the last Office Action are withdrawn. The following rejection constitutes the only rejection presently applied to the instant claims.

Claims 10-14, 33 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, and, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to practice the invention. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession

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of the claimed invention. The subject matter presently under consideration is drawn to the administration of the compound of instant claim 33, N-[(4-aminocyclohexyl)methyl]-2,3,5,8-tetrahydro-1,3-dioxo-2-[2-(phenylsulfonyl)ethyl]-1H-[1,2,4]triazolo[1,2-a]pyridazine-5-carboxamide, to inhibit any kinase. There is insufficient written description for this method in the disclosure.

Although kinase inhibitors are known in the prior art to treat various diseases, in the present disclosure there is no description of critical parameters or working examples that would lead one skilled in the medical arts to immediately envisage a predictable outcome comprising administering the elected compound among the thousands that are encompassed in the claim language.

Adequate description requires more than a mere statement that a particular compound inhibits a kinase selected from a cyclic AMP-dependent protein kinase A, a protein kinase C, a mitogen-activated protein kinase, or a calcium-dependent protein kinase and is part of the invention.

M.P.E.P. § 2163 states, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention...one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process."

Genetech Inc. vs. Nova Nordisk states, “[A] patent is not a hunting license. It is not a reward for a search but a compensation for its successful conclusion and ‘patent protection’ is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable” (42 USPQ 2d 1001, Fed. Circuit, 1997).

It is not clear Applicants were in possession of the full scope of the claimed methods at the time the invention was made. The compound of instant claim 33 is depicted in Table 14, page 243, as compound #221-14. Based on the plethora of compounds encompassed in the instant disclosure, there is no reasonable expectation of success based merely on a showing of anti-thrombotic activity or protease inhibition comprising administering compounds that are structurally distinct from the elected specie. Applicants have failed to describe the administration of the elected specie in a method of inhibiting a kinase. Accordingly, claims 10-14, 33 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 3, 2009

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614